

**REMARKS**

Claims 1-11 are all the claims pending in the application. Claims 4-10 are withdrawn from consideration. Claims 1-3 are rejected.

The claims have been amended to distinguish over a product of nature by reciting that the polypeptide is an isolated polypeptide.

Claim 1 has also been amended to recite the meaning of CAP, as supported in the specification at page 1, line 7, and to recite that the upper number of amino acids deleted, substituted and/or inserted in the amino acid sequence of the second polypeptide is 3 amino acids, as supported in the specification at page 12, lines 16-24.

Claim 2 has been amended to recite that the homology constitutes a sequence identity of 98%, as supported in the specification at page 13, lines 4-12.

New claim 11 is supported in the specification at page 7, lines 24-26.

Accordingly, no question of new matter arises, and entry of the amendments is requested, respectfully.

**A) Election/Restriction**

The Examiner acknowledged Applicants' election of Group I, claims 1-3 without traverse. Accordingly, claims 4-10 have been withdrawn from further consideration.

**B) Claim Objections**

The Examiner objected to claims 1-3 because the letters "CAP" are used without defining what they stand for.

Claim 1 has been amended to recite that the letters "CAP" stand for c-Cbl-associated protein, as supported at page 1, line 7 of the specification.

**C) Claim Rejections - 35 U.S.C. § 101**

Claims 1-3 were rejected under 35 U.S.C. § 101 because the claimed invention is allegedly directed to non-statutory subject matter.

The Examiner stated that the rejection would be withdrawn if the claims were amended to recite that the polypeptides are "isolated and purified."

The claims have been amended to recite that the polypeptides are isolated. Products of nature are not isolated.

Accordingly, reconsideration and withdrawal of this rejection are requested, respectfully.

**D) Claim Rejections - 35 U.S.C. § 112, second paragraph**

Claim 2 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

The Examiner asserted that it is not accurate to refer to sequence identity as "homology." The Examiner recommended that claim 2 be amended to refer to "identity" rather than homology.

The Examiner's suggestion has been adopted.

**E) Claim Rejections - 35 U.S.C. § 112, first paragraph**

Claims 1 and 2 were rejected under 35 U.S.C. § 112, first paragraph as lacking enablement and written description support in the specification.

The Examiner asserted that claims 1 and 2 lack enablement because there is no teaching in the specification as to how to make the second recited polypeptide of claim 1 that consists of an amino acid sequence in which 1 to 10 amino acids are deleted, substituted and/or inserted and which still maintains activity to bind CAP. The Examiner further asserted that the specification does not teach how to make polypeptides that have 90% or more sequence identity and still maintain activity to bind to CAP. In particular, the Examiner asserted that even though Applicants have provided examples of polypeptides that meet the limitations of claims 1 and 2, the specification does not teach which particular amino acids are necessary for activity. The Examiner concluded that undue experimentation would be required to make all possible polypeptides that fall within claims 1 and 2.

The Examiner asserted that the specification does not contain a written description of the genus of polypeptides encompassed by claims 1 and 2. Again, the Examiner asserted that the specification needs to disclose a correlation between function and structure in order to provide a written description commensurate in scope with the scope of the claims.

For the following reasons the rejections are overcome.

Claim 1 has been amended to recite that the maximum number of amino acids deleted, substituted, and/or inserted is 3. Further, claim 2 has been amended to recite that the percent sequence identity is 98%.

In this respect, the specification discloses SEQ ID NO:2 and SEQ ID NO:4 which has a three amino acid insertion in the sequence of SEQ ID NO:2. Please note that lines 18-23 of page 37 describe that SEQ ID NO:3 has a 9 base insertion in the sequence of SEQ ID NO:1. SEQ ID NO:1 and 3 are polynucleotide sequences respectively encoding SEQ ID NO:2 and 4 (cf. page 14, lines 12-15 of the specification).

SEQ ID NO:2 and SEQ ID NO:4 have a sequence identity of 98%.

In other words, focusing on SEQ ID NO:2, SEQ ID NO:4 is one example of the genus that is described in the specification. Focusing on SEQ ID NO:4, SEQ ID NO:2 is one example of the genus that is described in the specification. Accordingly, with respect to the polypeptide encompassed by claims 1 and 2, the genus is described in the specification. In this regard, Patent Guidance “REVISED INTERIM WRITTEN DESCRIPTION GUIDELINES TRAINING MATERIALS,” Example 14, indicates that the description requirement is met for a variant having a sequence identity of at least 95%, even if the specification discloses only the center sequence therein.

The method for preparing the protein consisting of the amino acid sequence of SEQ ID NO:2 or 4 and a method for measuring the binding with CAP are described in the specification, especially, in Examples 1, 2 and 5. Accordingly, the specification clearly teaches “How to Make” for the polypeptide that consists of an amino acid sequence having a sequence identity of

98% or more with the amino acid sequence represented by SEQ ID NO:2 or 4, and is a protein that binds to CAP.

In view of the above remarks and amendments to the claims, the Examiner is requested, respectfully, to reconsider and remove these rejections.

**F) Claim Rejections - 35 U.S.C. § 102**

**I.** Claims 1 and 2 were rejected under 35 U.S.C. § 102(a) as being anticipated by Strausberg, *et al.* (PNAS, Dec. 2002, 99:16899-16903).

The Examiner asserted that Strausberg *et al.* disclose a protein sequence that is 96.6% identical to SEQ ID No:4 and 94.9% identical to SEQ ID No:2. Further, the Examiner asserted that with such high sequence identity, the polypeptide would inherently bind to CAP.

For the following reasons the rejection is overcome.

The Examiner asserted that the PNAS reference by Strausberg, et al. discloses a protein sequence having an identity of 96.6% with SEQ ID NO:4 of the present invention and an identity of 94.9% with SEQ ID NO:2 of the present invention. However, this reference does not disclose a protein sequence having an identity of 96.6% with SEQ ID NO:4 of the present invention and an identity of 94.9% with SEQ ID NO:2 of the present invention. Even assuming that a protein sequence having an identity of 96.6% with SEQ ID NO: 4 of the present invention and an identity of 94.9% with SEQ ID NO:2 of the present invention, such subject matter is not included in the scope of the amended claims. Accordingly, this reference does not destroy the novelty of the polypeptide of the amended claims.

II. Claims 1 and 2 were rejected under 35 U.S.C. § 102(b) as being anticipated by Cronshaw, *et al.* (J. Cell Biology, Sept. 2002, 158(5):915-927).

The Examiner asserted that Cronshaw *et al.* teach a polypeptide that has 96% sequence identity to SEQ ID No: 2. Further, the Examiner asserted that with such high sequence identity, the polypeptide would inherently bind to CAP.

The polypeptide described in Cronshaw, *et al.* (polypeptide of accession No. AAM76703) is not included in the scope of the amended claims. Accordingly, this reference does not destroy the novelty of the polypeptide of the amended claims.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,


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